

United States Department of Agriculture
Food Safety and Inspection Service, Office of Public Health Science

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Title: FSIS Laboratory Regulatory Sample Pathogen Methods Table and Definitions		
Revision: 11-15-10	Replaces: NA	Effective: 11-15-10

Analyte	Microbiology Laboratory Guidebook Chapter #	Screen Test	Confirmatory Tests (following culturing on tube and plating media; and for <i>E. coli</i> O157:H7 IMS bead capture)	Days to Reporting: Screen Negative	Days to Reporting: Potential + Result	Days to Reporting: Presumptive + Result	Days to Reporting: Final + Result
<i>E. coli</i> O157:H7	MLG 5A MLG 5	BAX [®] PCR Assay (alternatives: lateral flow devices – RapidChek [®] or Transia [™])	<u>Serological confirmation:</u> <i>E. coli</i> O157:H7 latex agglutination test kit (RIM [®]) <i>E. coli</i> O157:H7 Latex Test Kit, REMEL) <u>Biochemical confirmation:</u> Vitek [®] GN/GNI/GNI Plus Cards (bioMerieux) <u>Shiga toxin/toxin genes confirmation:</u> Shiga Toxin test kit [Premier [®] EHEC, cat. # 608096 (Meridian Diagnostics, Inc)] or detection of toxin genes by PCR if needed	Day 2	Day 2 (Limited reporting)	Day 3	Day 5-7
<i>Non E. coli</i> O157 STEC (reporting mechanisms pending)	MLG 5B	<u>Multiplex RT PCRs:</u> eae, stx then wzx genes	<u>Multiplex RT PCR typical colonies</u> eae, stx then wzx genes <u>Biochemical confirmation:</u> Vitek [®] GN/GNI/GNI Plus Cards (bioMerieux)	Day 2	Day 2	Day 4	Day 5
<i>Listeria monocytogenes</i>	MLG 8 MLG 8A	BAX [®] PCR Assay	<u>Tumbling Motility observation</u> <u>Biochemical confirmation:</u> MICRO-ID [®] <i>Listeria</i> , <i>ListeriaAPI</i> [®] , Vitek 2 CAMP/CAMP Factor Test β-lysin CAMP factor discs (Remel) with MICRO-ID [®] ; Genetic Identification Testing if needed for speciation – GenProbe Accuprobe [®] Ribosomal RNA-based <i>L. monocytogenes</i> -specific test system	Day 3	NA	Day 4-5	Day 5-8

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<i>Salmonella</i> spp.	MLG 4 MLG 4C	BAX [®] PCR Assay	<u>Serological confirmation:</u> Somatic(O)Antigen Agglutination Tests (<i>Salmonella</i> polyvalent O antiserum); Flagellar (H) Antigen Agglutination Tests (Oxoid <i>Salmonella</i> Latex Test) <u>Biochemical confirmation:</u> Vitek [®] GNI/GNI Plus Cards (bioMerieux)	Day 2	NA	Day 5 NA for HACCP	Day 6-7 Depends on Vitek result available Day 6 PM; Day 7 AM
<i>Campylobacter</i> for Quantitative method	MLG 41	Direct Plating	Typical colonies subject to same day: <u>Microscopic examination</u> <u>Latex agglutination</u>	Day 3	NA	NA	Day 3

*Table doesn't include additional non regulatory testing (e.g.NVSL serotyping, PFGE subtyping, *Campylobacter* qualitative testing).
On Day 1 sample arrives in the laboratory. Days listed do not include delays (e.g. restreak for purity).

Definitions:

Potential positive *E. coli* O157:H7 – Enrichment medium from one or more subsamples yields a positive when screen tested.

Presumptive positive *E. coli* O157:H7 – One or more typical colonies on Rainbow agar agglutinate when tested with O157 antiserum.

Confirmed positive *E. coli* O157:H7 – One or more isolates from the sample is a biochemically identified *Escherichia coli* that is serologically or genetically determined to be “O157” that meets at least one of the following criteria:

- 1) Positive for Shiga toxin (ST) production
- 2) Positive for Shiga toxin gene(s) (stx)
- 3) Genetically determined to be “H7”

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Potential positive non *E. coli* O157 STEC – Enriched medium from a sample which yields a positive when screened on real-time PCR for each of the targeted genes (*eae*, *stx1/2*, and *wzx*) of one of six non-O157 serogroups (O26, O45, O103, O111, O121, O145).

Presumptive positive non *E. coli* O157 STEC – One or more typical colonies on Rainbow agar. Colony is positive by Multiplex PCR tests for *eae* and *stx* then *wzx* genes.

Confirmed positive non *E. coli* O157 STEC – One or more isolates from the sample is confirmed positive on real-time PCR for the *eae*, *stx*, and *wzx* genes of one of six non-O157 serogroups and biochemically identified as *Escherichia coli*.

Presumptive positive *L. monocytogenes* – A sample from which one or more typical colonies produces beta hemolysis on Horse Blood Agar.

Confirmed positive *L. monocytogenes* – A beta hemolytic isolate is Camp test positive, shows tumbling motility (optional) and is characterized biochemically as *L. monocytogenes*. Ribosomal RNA testing is occasionally required to resolve atypical strains.

Presumptive positive *Salmonella* spp. – A sample yields one or more isolates which show typical appearance on TSI and LIA slants and agglutinate salmonella somatic antisera.

Confirmed positive *Salmonella* spp. – *Salmonella* O group positive isolates are characterized biochemically as *Salmonella* spp.

Confirmed positive *Campylobacter* – Typical colony morphology, microscopic ID, latex agglutination positive for *C. jejuni*, *C. coli*, and *C. lari*.